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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,195	12/19/2001	David Berd	1225/1D414US2	8483

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,195	BERD, DAVID	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *2,3,6 and 9-22* is/are pending in the application.

4a) Of the above claim(s) *3, 9-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,6 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/14/02, 8/3/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed June 13, 2005 is acknowledged and has been entered. Previously pending claims 1, 7, 8, 23, 24 have been canceled, claims 2, 6 and 22 have been amended. Claims 2-3, 6, 9-22 are currently pending, claims 3 and 9-21 remain withdrawn from consideration and claims 2, 6 and 22 are currently under prosecution. An action on the RCE follows.

2. It is noted that Applicant requests the cancellation, on page 2 of the Response, of claims 1, 4, 5 which were previously canceled in the paper submitted March 8, 2004. Although Applicant has not requested the cancellation of claims 7, 8, 23-24 on page 2 of the response, the listing of the claims clearly indicates that claims 7, 8 and 23-24 are canceled and the Applicant states on page 5 of the response, first paragraph, that claims 7 and 8 have been canceled and in paragraph 2 under the heading of Restrictions/Elections as drawn to claims 23 and 24 that "Applicant hereby cancels claims 23 and 24. Therefore, the Office considers that claims 7, 8, 23 and 24 are canceled.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 2, 6 and 22 remain rejected, under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed May 24, 2004, Section 5, pages 3-4.

Applicant argues that the rejection is rendered moot in view of Applicant's amendment of claim 2 to delete reference to the term "substantially".

The argument has been considered but has not been found persuasive because although Applicant responded to some of the arguments set forth in the paper submitted March 3, 2004, the claims remained rejected for the reasons set forth in the Paper mailed September 3, 2003. Applicant argued in the paper submitted May 3, 2004 that the specification makes clear that "substantially in a state of no growth" refers to cells which are not going to grow and divide after administration such that they are cells that will not divide *in vivo*. Examiner pointed out that the phrase "cells that will not divide *in vivo*" is not drawn to the term "substantially" but is drawn to cells in a state of no growth. Apparently in response to Examiner's statement's Applicant has amended the claims to delete the term "substantially". However, this does not overcome the rejections of record because although the specification states that "It is understood that "cells in a state of no growth' means live or killed.....cells that will not divide *in vivo*", the claim is not drawn to cells in a state of no growth, but rather are drawn to cells in a no growth state which reads on attenuated cells which, for the reasons set forth in the paper mailed September 3, 2003, are not permanently in a no growth phase and which would be expected to return to a "growth phase" and the rejection of record drawn to cells not permanently in a no growth phase remain. Although Applicant previously argued that methods for suspending cells in a state of no growth were well-known in the art, other than conventional irradiation, as previously set forth, no methods of suspending the cells in a state of no growth are taught. Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained. It is noted that amendment of claim 2, for example to recite

"irradiated colon carcinoma cell" would unambiguously define the claimed invention and would obviate this grounds of rejection.

Claim Rejections - 35 USC § 103

5. Claims 2, 6, 22 remain rejected under 35 USC 103 for the reasons previously set forth in the Paper mailed May 24, 2004, Section 7, pages 5-7.

Applicant essentially reiterates arguments set forth in the Response filed March 8, 2004 and argues that Examiner has not met the burden of establishing a *prima facie* case of obviousness and points to the MPEP, in particular (a) there is no disclosure in either reference that would motivate a person of ordinary skill in the art to combine one reference with the other since nothing in Hoover motivates one to try haptenizing the tumor cells of the vaccine taught in Hoover and nothing in the '551 patent motivates the reader to haptenize the tumor cell of Hoover et al, (b) even if the references were combined there could be no reasonable expectation of success in producing a haptenized tumor cell since nothing is indicated in either reference that colon carcinoma could be treated by administering a haptenized tumor cell vaccine.

The arguments have been considered but have not been found persuasive because (a') the MPEP clearly teaches that the motivation can come from either the reference themselves or in the knowledge generally available to one of ordinary skill in the art. As previously set forth, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is clear

that, as previously set forth, given the method of Hoover et al which successfully treated colon cancer, given the improvement in T-lymphocyte infiltration to the tumor directly attributable to the haptenization of a whole cell vaccine and the teachings of the '551 that specifically state that haptenization of tumor cells leads to increased infiltration into the tumor mass and that this is a significant advance in the art, given the teaching that most tumor immunologists agree that getting T lymphocytes into the tumor mass is a prerequisite for tumor destruction by the immune system, given the teaching that the haptenization approach increases the number and capacity of lymphocytes entering the tumor, the motivation to combine the references is clear in that one would have been motivated to improve the efficacy of the already successful method of Hoover et al by improving T-lymphocytes infiltration into the tumor mass by the simple, successful, haptenization method of the '551 patent, (b') as previously set forth, given that even without haptenization the colon cancer vaccine of Hoover et al was successful. Further, the '551 patent clearly teaches conventional methods of conjugating DNP to a cell and it would have been expected that once conjugated, given the teaching of the '551 patent, that the efficacy of the already successful vaccine process for the treatment of colon cancer would have been increased with the conjugation of the cells to DNP for the reasons of record. Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained.

6. All other objections and rejections recited in the previous Final Rejection are hereby withdrawn.

7. No claims allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached Monday through Thursday from 6:00am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
August 10, 2005